

117TH CONGRESS
1ST SESSION

H. R. 5377

To facilitate the development of treatments for cancers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 2021

Mr. BUTTERFIELD (for himself and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To facilitate the development of treatments for cancers, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Cancer Patient Equity
5 Act of 2021”.

6 **SEC. 2. COVERAGE OF CANCER DIAGNOSTIC AND LABORA-**
7 **TORY TESTS.**

8 (a) MEDICARE.—

1 (1) COVERAGE.—Section 1861 of the Social Se-
2 curity Act (42 U.S.C. 1395x) is amended—

3 (A) in subsection (s)(2)—

4 (i) in subparagraph (GG), by striking
5 “and” at the end;

6 (ii) in subparagraph (HH), by strik-
7 ing the period at the end and inserting “;
8 and”; and

9 (iii) by adding at the end the fol-
10 lowing new subparagraph:

11 “(II) cancer diagnostic and laboratory tests (as
12 defined in subsection (III)) furnished on or after the
13 date that is 6 months after the date of the enact-
14 ment of this subparagraph.”; and

15 (B) by adding at the end the following new
16 subsection:

17 “(III) CANCER DIAGNOSTIC AND LABORATORY
18 TESTS.—

19 “(1) IN GENERAL.—The term ‘cancer diag-
20 nostic and laboratory tests’ means—

21 “(A) microarray analysis, DNA sequenc-
22 ing, RNA sequencing, whole-exome sequencing,
23 and other forms of next-generation sequencing
24 furnished and reported by a clinical laboratory

1 (as defined in section 353(a) of the Public
2 Health Service Act); and

3 “(B) explanation and interpretation of any
4 analysis or sequencing described in subpara-
5 graph (A);

6 furnished to an individual diagnosed with cancer.

7 “(2) FREQUENCY.—Tests described in para-
8 graph (1) may only be furnished with respect to an
9 individual diagnosed with a cancer—

10 “(A) once upon the diagnosis of such can-
11 cer;

12 “(B) once upon any recurrence of such
13 cancer; and

14 “(C) as necessary for purposes of moni-
15 toring the progression of such cancer or the re-
16 sponse of such cancer to treatment.”.

17 (2) PAYMENT.—Section 1833 of the Social Se-
18 curity Act (42 U.S.C. 1395l) is amended—

19 (A) in subsection (a)(1)—

20 (i) by striking “and (DD)” and in-
21 serting “(DD)”; and

22 (ii) by striking “;” and inserting “,
23 and (EE) with respect to cancer diagnostic
24 and laboratory tests (as defined in section
25 1861(III)), the amount paid shall be an

1 amount equal to 80 percent (or 100 per-
2 cent, in the case of such tests for which
3 payment is made on an assignment-related
4 basis) of the lesser of the actual charge for
5 the test or the amount that would have
6 been determined for such test under sec-
7 tion 1834A had such test been a clinical
8 diagnostic laboratory test;” and

9 (B) in subsection (b)—

10 (i) by striking “and (12)” and insert-
11 ing “(12)”; and

12 (ii) by striking “section
13 1861(s)(10)(A).” and inserting “section
14 1861(s)(10)(A), and (13) such deductible
15 shall not apply with respect to cancer diag-
16 nostic and laboratory tests (as defined in
17 section 1861(III)).”.

18 (3) EXCLUSION MODIFICATION.—Section
19 1862(a)(1) of the Social Security Act (42 U.S.C.
20 1395y(a)(1)) is amended—

21 (A) in subparagraph (O), by striking
22 “and” at the end;

23 (B) in subparagraph (P), by striking the
24 semicolon and inserting “, and”; and

1 (C) by adding at the end the following new
2 subparagraph:

3 “(Q) in the case of cancer diagnostic and lab-
4 oratory tests (as defined in section 1861(III)), which
5 are performed more frequently than is covered under
6 such section;”.

7 (b) MEDICAID.—

8 (1) INCLUSION AS MEDICAL ASSISTANCE.—Sec-
9 tion 1905(a) of the Social Security Act (42 U.S.C.
10 1396d(a)) is amended—

11 (A) in paragraph (30), by striking “and”
12 at the end;

13 (B) by redesignating paragraph (31) as
14 paragraph (32); and

15 (C) by inserting after paragraph (30) the
16 following new paragraph:

17 “(31) cancer diagnostic and laboratory tests (as
18 defined in section 1861(III)); and”.

19 (2) MANDATORY COVERAGE.—Section
20 1902(a)(10)(A) of such Act is amended, in the mat-
21 ter preceding clause (i), by striking “and (30)” and
22 inserting “(30), and (31)”.

23 (3) INCLUSION IN BENCHMARK COVERAGE.—
24 Section 1937(b)(5) of such Act is amended by in-
25 serting before the period at the end the following: “,

1 and beginning January 1, 2022, coverage of cancer
2 diagnostic and laboratory tests (as defined in section
3 1861(III))”.

4 (4) EFFECTIVE DATE.—

5 (A) IN GENERAL.—The amendments made
6 by this section shall apply with respect to items
7 and services furnished on or after January 1,
8 2022.

9 (B) EXEMPTION FOR STATE LEGISLA-
10 TION.—In the case of a State plan under title
11 XIX of the Social Security Act (42 U.S.C. 1396
12 et seq.), or waiver of such plan, that the Sec-
13 retary of Health and Human Services deter-
14 mines requires State legislation in order for the
15 respective plan to meet any requirement im-
16 posed by amendments made by this section, the
17 respective plan shall not be regarded as failing
18 to comply with the requirements of such title
19 solely on the basis of its failure to meet such
20 an additional requirement before the first day
21 of the first calendar quarter beginning after the
22 close of the first regular session of the State
23 legislature that begins after the date of the en-
24 actment of this Act. For purposes of the pre-
25 vious sentence, in the case of a State that has

1 a 2-year legislative session, each year of the ses-
2 sion shall be considered to be a separate regular
3 session of the State legislature.

4 (c) CHIP.—Section 2103(c) of the Social Security
5 Act (42 U.S.C. 1397cc(c)) is amended by adding at the
6 end the following new paragraph:

7 “(11) COVERAGE OF CANCER DIAGNOSTIC AND
8 LABORATORY TESTS.—Regardless of the type of cov-
9 erage elected by a State under subsection (a), begin-
10 ning January 1, 2022, child health assistance pro-
11 vided under such coverage for targeted low-income
12 children and, in the case that the State elects to pro-
13 vide pregnancy-related assistance under such cov-
14 erage pursuant to section 2112, such pregnancy-re-
15 lated assistance for targeted low-income pregnant
16 women (as defined in section 2112(d)), shall include
17 coverage of cancer diagnostic and laboratory tests
18 (as defined in section 1861(III)).”.

19 **SEC. 3. EDUCATION AND AWARENESS PROGRAM ON**
20 **GENOMIC TESTING.**

21 (a) IN GENERAL.—The Secretary of Health and
22 Human Services, in coordination with the Director of the
23 National Human Genome Research Institute, shall carry
24 out an education and awareness program for physicians

1 and the general public on what genomic testing is, how
2 can be used, and the role of genetic counselors.

3 (b) CANCER AND MOLECULAR DIAGNOSTICS.—The
4 education and awareness program under subsection (a)
5 shall encourage the inclusion in graduate medical edu-
6 cation and continuing medical education (including for
7 specialty oncology services) of education and training on
8 the importance of molecular diagnostics at diagnosis and
9 reoccurrence of cancer to detect mutations.

○